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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/509,677	Applicant(s) II ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2002 and 12 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-20 and 26-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-20 and 26-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

The request filed on September 12, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/509,677 is acceptable and a CPA has been established. An action on the CPA follows.

Applicant's amendments filed September 12, 2002 have been entered. The addition of claims 26-31 in the amendments filed September 12, 2002 is acknowledged.

Claims 1, 3-20 and 26-31 are pending.

The rejection under 35 USC 112, second paragraph regarding "corrective agents" has been withdrawn in view of the amendments filed September 12, 2002.

Specification

The amendment filed September 12, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "flavoring agents" is new matter because such term was not disclosed nor recited in the originally filed specification or claims.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As discussed in the advisory action mailed October 1, 2002, flavoring agents are not disclosed or recited in the originally filed specification or claims. Applicants are required to cancel the new matter recited in the claims in the reply to this Office Action.

Claims 1 and 3-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that define a drug with "at least one basic group in its structure, thereby renders the unpleasant taste". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. There is no adequate direction provided by the applicant as to how to select other unpleasant tasted drugs with at least one basic group in its structure which would be suitable in the instant invention. It is known that aspartame contains an amino group, which is a basic group according to the definition disclosed in the instant specification page 5, second paragraph (See Merck Index, 11th ed., monograph 861). Nevertheless, aspartame does not have an unpleasant taste because it is known to be useful as a sweetener. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. Applicant has not provided sufficient biochemical information (e.g. molecular weight, melting point, refractive index, etc.) that distinctly identifies compounds other than those encompassed by compounds having unpleasant taste. While a "drug with at least one basic group in its structure, thereby renders the unpleasant taste" may have some

notion of the activity of the "drug"; claiming biochemical molecules by function only fails to enable the skilled artisan to make and use the scope of such molecules, as there is insufficient guidance and direction as to structure of the limitation "drug with at least one basic group in its structure, thereby renders the unpleasant taste", broadly encompassed by the claimed invention.

Furthermore, the instant specification does not provide any working examples to point out how other drugs with at least one basic group in its structure, thereby renders the unpleasant taste, may be used successfully in the claimed invention. In other words, only a limited number of drugs with " at least one basic group in its structure, thereby renders the unpleasant taste" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity.

Moreover, it is well known in the art that structural differences in active compounds will impart different chemical, physical, and therapeutic properties to the same compounds. Therefore different drug compounds with unpleasant tastes, other than the ones listed in specification from page 6, line 15 to page 8, line 5, may be reasonably expected to yield a different result (See the aspartame example discussed above). The instant claims read on all drugs with " at least one basic group in its structure, thereby renders the unpleasant taste ", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 3-20, 29, 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "unpleasant taste" in claim 1, 9, and 19 is a relative term which renders the claim indefinite. The expression "unpleasant taste" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant's remarks regarding the specification page 5, lines 5-14 lists examples of drugs having unpleasant taste have been considered but are not found persuasive because even though the specification page 5, lines 5-14 lists some examples of drugs having unpleasant taste, it is still unclear what drugs are encompassed by the claims because these examples are neither exhaustive, nor define the class of compounds required. It is unclear what agents other than example compounds disclosed are encompassed by this term. Please note that the term "unpleasant taste" is very subjective and may based on the experience of the beholder. For example, the specification, page 21-25 discloses a test and the applicant remarks that the sensory test of bitterness provide the standard for ascertain the degree of bitterness. However, even the different panel members would feel differently towards the same formulations. In Table 2 on page 22 in the specification, more than one

incidence, different panelist has different marks given to the same formulation tasted. Because unpleasant taste and bitter taste are relative terms, the claims are properly rejected under 35 USC 112, second paragraph. For example, some may not like broccoli because of its unpleasant taste

The expression "bitter taste" in claim 2 is a relative term which renders the claim indefinite. The expression "bitter taste" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to what drugs are encompassed by the claims. Applicant's remarks regarding definition of "bitter taste" is disclosed in the specification have been considered but are not found persuasive because some compounds are bitter to some but not to others. It is unclear what agents other than example compounds disclosed are encompassed by this term. Again, please note that the term "bitter taste" is very subjective and may based on the experience of the beholder. For example, the specification, page 21-25 discloses a test and the applicant remarks that the sensory test of bitterness provide the standard for ascertain the degree of bitterness. However, even the different panel members would feel differently towards the same formulations. In Table 2 on page 22 in the specification, more than one incidence, different panelist has different marks given to the same formulation tasted. Because bitter taste and bitter taste are relative terms, the claims are properly rejected under 35 USC 112, second paragraph.

The expression "crude drug selected from ...sophorae radix" in claim 30 renders the claim indefinite as to what active compounds are encompassed by the claims. There are many actives in herbal products, it is not clear what compounds would be considered as "crude drugs".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7, 9, 12-14, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Pearmain (US Patent 5,188,839), reference of record.

Pearmain teaches cimetidine tablet, which improve palatability, that consists essentially of a pH adjusting agents: sodium bicarbonate, a sugar alcohol: sorbitol and a sweetener: aspartame (See particularly the abstract, col.4, example 3). Pearmain also teaches the ratio between sorbitol and cimetidine is about 3.5 to 1; the ratio between sodium bicarbonate and cimetidine is about 0.9 to 1 (See particularly col. 4, example 3).

Claims 1 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Behrakis et al. (US Patent 3,928,609).

Behrakis et al. teaches an oral theophylline pharmaceutical composition consisting essentially of Theophylline, sorbitol, a sugar alcohol, and a pH adjusting agent, citric acid (See col. 3, line 25-43).

Claims 1 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Breillatt, Jr et al. (US Patent 5,510,115).

Breillatt, Jr et al. teaches an ampicillin oral composition consisting essentially of sorbitol (a sugar alcohol), ampicillin, and sodium bicarbonate (a pH adjusting agent) See col. 6, line 22-27).

Claims 1, 26, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Mercer et al. (US Patent Re. 29,875).

Mercer et al. teaches an oral composition consisting essentially sorbitol, ephedrine hydrochloride, theophylline, and citric acid (See col. 3, the Example; and claim 1).

Response to Remarks regarding rejection under 35 USC 102

Applicant's arguments averring Pearmain not anticipating the instant invention since Pearmain teaches an additional ingredient polymethacrylate polymer, have been considered but are not found persuasive. The instant claims are directed to "a composition ...consisting essentially of ...". The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and those

that do not materially affect the basic and novel characteristic of the claimed invention. For the purpose of searching for and applying prior art under 35 USC 102 and 103, absent clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising" See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by `consisting essentially of' language.") (See MPEP 2111.03). In the instant case, it is the applicant's burden to show that the addition of polymethacrylate polymer would change the basic and novel characteristics

of the instant invention. Therefore, the claims herein are properly rejected under 35 US 102 over Pearmain, absent evidence to the contrary. No such evidence is present herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 10-11, 15, 19, 20, 28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearmain (US Patent 5,188,839) in view of Hoshino (WO 97/12606, English equivalent, US Patent 6,146,661, is also provided).

Pearmain teaches cimetidine tablet, which improve palatability, that consists essentially of a pH adjusting agents: sodium bicarbonate, a sugar alcohol: sorbitol and a sweetener: aspartame (See particularly the abstract, col.4, example 3). Pearmain also teaches the ratio between sorbitol and cimetidine is about 3.5 to 1; the ratio between sodium bicarbonate and cimetidine is about 0.9 to 1 (See particularly col. 4, example 3).

Pearmain does not expressly teach that erythritol, the sugar alcohol, is in the cimetidine tablet. Pearmain does not expressly teach that the ratio between the sugar alcohol to cimetidine is from 5 to 10 : 1. Pearmain does not expressly teach that the pH values of the solution of the pH adjusting agent be equal to or higher than that of the solution of cimetidine. Pearmain does not expressly teach a method of masking the

taste of an oral preparation employing the cimetidine tablet with improved palatability. Pearmain does not expressly teach the specific sugar alcohol amount. Pearmain does not expressly teach roxatidine employed in the composition.

Hoshino teaches a chewable tablet which may contain a H_2 receptor blocking agent including cimetidine or roxatidine, and erythritol (See abstract, claim 1). Hoshino also teaches a method of improving the unpleasant taste of the tablet with sugar alcohol herein, including erythritol (See col. 1, lines 51-58; col. 2, lines 25-56 particularly, and col. 6, line 1 to 60).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to employ the sugar alcohol, erythritol in the cimetidine tablet of Pearmain, with the ratio between the sugar alcohol to cimetidine being from 5 to 10 : 1 and the pH values of the solution of the pH adjusting agent be equal to or higher than that of the solution of cimetidine. It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the amount of sugar alcohol employed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute roxatidine for cimetidine in Pearsmain's composition.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to employ the cimetidine tablet in a method of improving "taking ability".

One of ordinary skill in the art would have been motivated to incorporate erythritol into the cimetidine tablet of Pearmain because it is known in the art that erythritol is useful to improve from unpleasant intrabuccal (oral) sensation in chewable tablet

compositions. The incorporation of erythritol to improve the taste of a cimetidine tablet is therefore *prima facie* obvious. One of ordinary skill in the art would have been motivated to substitute roxatidine for cimetidine in Pearsmain's composition because both roxatidine and cimetidine can be formulated into a composition with s sugar alcohol, erythritol to improve the palatability of the tablet. Based on the teachings of Hoshino, both roxatidine and cimetidine are considered candidate compounds that can be formulated into an oral formulation with erythritol. Selecting one over the other would be seen as a simple selection from among obvious alternatives, absent evidence to the contrary.

Optimization of result effect parameters (i.e., ingredient amounts, solutions, or suspension, pH values) is obvious as being within the skill of the artisan, absent evidence to the contrary.

One of ordinary skill in the art would have been motivated to employ the cimetidine tablet of Pearmain as modified by Hoshino in a method of improving taking ability because the tablet would be expected to have improved taste and oral sensation and therefore the tablet would have been reasonably expected to be more pleasant to "take" or ingest orally.

Response to Arguments

Applicant's rebuttal arguments filed November 12, 2002 averring Hoshino fails to teach the improvement of the unpleasant taste of drugs have been fully considered but they are not persuasive. This is seen to be irrelevant to the grounds of rejection under

35 USC 103(a) set forth in the instant office action. Please see claim 1, which teaches a composition having the preferred sugar alcohol, erythritol, and a gastrointestinal active such as cimetidine and roxatidine acetate. The ground of rejection under 35 USC 103 does not base on whether sucralfate is having an unpleasant taste or not. Please note that the claims herein are drawn to a composition. All the characteristics or properties of the product are not lending patentable weight.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
January 21, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER
1/25/05